IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| DEY, L.P. and DEY, INC., | ) | |
| | ) | |
| Plaintiffs, | ) | |
| | ) | |
| v. | ) | C.A. No. 08-372 (JJF) |
| | ) | |
| SEPRACOR INC., | ) | |
| | ) | |
| Defendant. | ) | |

**SEPRACOR'S OPENING BRIEF IN SUPPORT OF ITS**
**MOTION TO DISMISS PURSUANT TO FED. R. CIV. P. 12(b)(1)**

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## NATURE AND STAGE OF THE PROCEEDING

On June 20, 2008, Dey filed this action seeking a declaratory judgment of non-infringement and invalidity of Sepracor's U. S. Patent No. 6,451,289 (the "'289 patent"). Sepracor and Dey have been litigating over the same product and over five other patents since early 2006. Sepracor has moved, pursuant to FED. R. CIV. P. 12(b)(1), to dismiss this declaratory judgment action. This is Sepracor's opening brief in support of that motion.

## SUMMARY OF ARGUMENT

There is no justiciable controversy regarding Dey's infringement or the validity of the '289 patent. Sepracor has never threatened to sue Dey for infringement of the '289 patent, and Dey apparently has never believed itself under any threat of suit. Indeed, despite its January 9, 2006 Paragraph IV notice letter addressing the '289 patent and despite the patent litigation between the parties on-going for the last two years on five other Sepracor patents covering Dey's ANDA product, Dey never sought a declaratory judgment regarding the '289 patent until now. Further, to eliminate any possible argument that there is any apprehension of suit, Sepracor has now given Dey a covenant not to sue on the '289 patent.

Dey was not the first generic company to file an ANDA seeking approval to market a generic version of Sepracor's highly successful Xopenex® product for the treatment of bronchial disorders like asthma. Breath Ltd. ("Breath") filed the first ANDA on three strengths of generic Xopenex® with a Paragraph IV certification addressing all six Orange Book patents covering Xopenex®. Accordingly, Breath, the so-called "first-filer," is eligible for 180 days of exclusivity on each of those six patents with respect to those three strengths. After a recent Markman hearing in the Breath action, during which the Judge ruled from the bench in Sepracor's favor on two key claim construction disputes, Breath settled its litigation with Sepracor on all six patents. As a result of that settlement, Breath will enter the market by August 20, 2012 with a

royalty-bearing license from Sepracor covering those patents. At that time, Breath's expected 180-day exclusivity period on all six patents will begin to run.

Dey apparently brought this suit in the hope of triggering Breath's expected 180-day exclusivity on the '289 patent -- the patent that it has deliberately ignored during the two-year pendency of the existing patent litigation between the parties, and for which it now has an unqualified covenant not to sue. Dey will likely argue that the 180-day exclusivity that Breath should enjoy as a result of being the first-filer, the very reward that the framers of the Hatch-Waxman Act suit envisioned to incentivize first-filers of Paragraph IV patent challenges, is causing it an "injury" of delayed market entry somehow traceable to Sepracor's conduct. Thus, Dey will likely argue that it is entitled to maintain this declaratory judgment to remedy its alleged "injury" under the Federal Circuit's recent *Caraco* decision.[1]

But *Caraco* does not apply under the facts present here, and thus does not control the outcome. In *Caraco*, the Federal Circuit emphasized that the alleged "injury" from which the declaratory judgment plaintiff sought relief must be actual and immediate, not conjectural or hypothetical. In that case, the Federal Circuit concluded that the ability of the declaratory judgment plaintiff to maintain its declaratory judgment action actually, immediately and necessarily affected its market entry.

Here, the ability of this declaratory judgment action to affect Dey's market entry is completely hypothetical, if not outright unlikely. Two of Sepracor's patents in the pending lawsuit between the parties expire after Breath's expected 180 days of exclusivity will expire. If Sepracor emerges from that lawsuit with just one of the six asserted claims from those two patents found to be valid and infringed, then Dey will be barred from entering the market with its

[1] *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008).

generic Xopenex® products until after Breath's expected 180 days of exclusivity has already expired. In that case, Breath's expected 180-day exclusivity will be irrelevant to Dey's market entry. *Caraco* does not mandate that this Court clog its docket with a discretionary declaratory judgment action where the plaintiff's ability to redress its alleged injury is merely conjectural.

Finally, Dey has one generic Xopenex® strength (the "concentrate") that is not even affected by Breath's expected 180 days of exclusivity. By early 2009, there will be no further regulatory hurdles preventing Dey from marketing this product.

Because Dey cannot show that its alleged injury is actual and immediate, as opposed to hypothetical and speculative, *Caraco* and Supreme Court precedent dictate that Dey cannot pursue this declaratory judgment action. Accordingly, Sepracor's motion to dismiss should be granted.

## STATEMENT OF FACTS

Sepracor developed and markets Xopenex®, a drug product containing the active ingredient levalbuterol (a beta-adrenergic compound), used in the treatment of bronchial disorders such as asthma.

As authorized by 21 U.S.C. § 355(b)(1), Sepracor listed in the FDA's Orange Book six patents relating to Xopenex®, namely U.S. Patent Nos. 5,362,755 (the "'755 patent"); 5,547,994 (the "'994 patent"); 5,760,090 (the "'090 patent"); 5,844,002 (the "'002 patent"); 6,083,993 (the "'993 patent"); and the '289 patent (collectively the "Orange Book patents").

Sepracor listed these six patents in the Orange Book because they cover Sepracor's Xopenex® drug products. 21 U.S.C. § 355(b)(1) ("[t]he applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with

respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."). Failing to list patents subjects the applicant to various penalties. 21 U.S.C. § 355(e)(4); 21 C.F.R. § 314.150(a)(2)(v).

On July 14, 2005**,** Dey filed Abbreviated New Drug Application ("ANDA") No. 77-800 (its "first ANDA"), seeking to market 0.31 mg/3ml, 0.63 mg/3ml and 1.25 mg/3ml strengths of a generic version of Sepracor's Xopenex® inhalation solution product. In a letter dated January 9, 2006, Dey notified Sepracor of its ANDA filing and provided a so-called Paragraph IV Certification notice letter (pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(iv)) alleging that all six Xopenex® Orange Book patents are invalid and/or not infringed. Dey's 2006 letter specifically addressed the '289 patent, the subject of Dey's Declaratory Judgment Complaint in this action filed June 20, 2008. (Exh. 1)[2].

On February 22, 2006, nearly two-and-a half years ago, Sepracor sued Dey on five of the six Orange Book patents ("the first action") in response to Dey's January 2006 notice letter. Significantly, Sepracor did not sue Dey on the '289 patent in February 2006. *See* D.I. 1, *Sepracor Inc. v. Dey, L.P. and Dey, Inc.*, C.A. No. 06-113-JJF. On June 7, 2006, Dey filed an Answer and Counterclaims in the first action. Dey, however, did not assert a Declaratory Judgment counterclaim involving the '289 patent. At no time since have the parties discussed a possible lawsuit over the '289 patent. Sepracor has not threatened suit, nor has Dey ever requested a covenant not to sue on the '289 patent.

[2] "Exh. __" refers to exhibits attached to the accompanying August 13, 2008 Declaration of Preston K. Ratliff II.

Although the thirty-month stay has expired in the first action, Dey has not received final FDA approval of its first ANDA. About a month before Dey filed its first ANDA with a Paragraph IV certification on three strengths of generic Xopenex®, another generic drug company, Breath, filed an ANDA with a Paragraph IV certification on these same three strengths. Thus, Breath is the so-called "first-filer" and is entitled to 180 days of exclusivity on these three strengths.

On October 21, 2005, Sepracor sued Breath on all six Xopenex® Orange Book patents in the United States District Court for the Northern District of Illinois (this suit was later transferred to the District Court of Massachusetts). Because Breath was the first ANDA applicant to file a Paragraph IV certification on all six Orange Book patents, Breath is entitled to 180 days of exclusivity vis-à-vis all subsequent ANDA filers, including Dey, on the three strengths at issue, for *each* of the six patents. 21 U.S.C. § 355(j)(5)(B)(iv). The framers of the Hatch-Waxman Act built in the 180-day exclusivity for the first Paragraph IV certifying ANDA filers to "incentivize ANDA filers to challenge the validity of listed patents or design around those patents as early as possible…," to hasten the availability of generic drugs. *Caraco Pharm. Labs., Ltd. v Forest Labs., Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008).

The Massachusetts District Court held a Markman hearing in the Breath litigation on March 27, 2008. Judge Woodlock ruled from the bench at that hearing in Sepracor's favor on two of the primary claim construction disputes, while reserving decision on the remaining disputes. (Exh. 2, Markman Tr. 6:21-7:8 & 19:19-21). Before the Court issued its formal, final written Markman ruling, however, Breath settled its litigation with Sepracor. In relevant part, the settlement agreement permits Breath to enter the market with its generic Xopenex® product on August 20, 2012, pursuant to a royalty-bearing patent license. (Exh. 3). Significantly, that is

***one year*** before the expiration date of the latest-to-expire of the five patents (the '994 patent) that Dey has been sued on in the first action, and ***seven months*** before the expiration of the '755 patent.

Dey filed ANDA No. 78-309 ("second ANDA"), seeking approval to market a "concentrate" strength of generic Xopenex®, and provided a notice of Paragraph IV certification to Sepracor on all six Orange Book patents on August 14, 2006. On September 27, 2006, within 45 days of receipt of that notice letter, Sepracor sued Dey, again asserting the same five patents as in the first action. *See Sepracor Inc. v. Dey, L.P. and Dey, Inc.*, C.A. No. 06-604-JJF. Dey filed its Answer and Counterclaims on October 23, 2006. Again, however, Dey did not file a declaratory judgment claim regarding the '289 patent. Dey has never requested a covenant not to sue in connection with the '289 patent and its second ANDA. Dey is the sole "first-filer" on the "concentrate" strength and is eligible to receive final ANDA approval as early as February 14, 2009, when the thirty-month stay expires. At that time, there will be no regulatory hurdle to Dey marketing this generic Xopenex® product. In other words, any 180-day exclusivity that Breath enjoys on the other strengths is irrelevant to Dey's market entry on the concentrate product. On December 5, 2006, the first and second Dey actions (06-113 and 06-604) were consolidated in this Court.

On August 12, 2008, although unsolicited, Sepracor provided Dey an unqualified covenant not to sue on the '289 patent covering the products of both of Dey's ANDAs. (Exh. 4). That covenant narrows the issues for the current motion to dismiss and, in particular, eliminates any argument that Dey is under any threat of suit under the '289 patent, although as discussed above, Dey had consciously ignored the '289 patent for over two years.

## ARGUMENT

### A. The Court Should Not Extend *Caraco* To The Facts Of This Case

As this Court has recognized, the Supreme Court in the *MedImmune* decision replaced the "reasonable apprehension of imminent suit test" for declaratory judgment jurisdiction in patent cases with a "totality of the circumstances test." *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 525 F. Supp. 2d 680, 686 (D. Del. 2007) (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 S. Ct. 764 (2007)). In particular, under *MedImmune*, the question whether declaratory judgment jurisdiction exists in patent cases turns on "whether the facts alleged, under all of the circumstances, show that there is a substantial controversy, between parties having adverse legal interest, ***of sufficient immediacy and reality*** to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127 S. Ct. at 771 (emphasis added) (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

Post-*MedImmune*, district courts have routinely held that a covenant not to sue given by the patentee to a declaratory judgment plaintiff divests the court of subject matter jurisdiction to hear the declaratory judgment claim. *See, e.g.*, *Pfizer*, 525 F. Supp. 2d at 686; *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, No. 06-1020, 2007 WL 3014702, at *3 (D. N.J. Oct. 11, 2007); *Merck & Co., Inc. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 425-26 (D. Del. 2007), *aff'd*, No. 2007-1362, 2008 WL 2753378 (Fed. Cir. July 16, 2008).

In *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008), a divided panel of the Federal Circuit held that, post-*MedImmune*, there are particular factual situations in ANDA litigation where declaratory judgment jurisdiction will exist notwithstanding a covenant not to sue. In *Caraco*, the undisputed sole first ANDA filer, Ivax, lost its validity challenge on one of the two Orange Book patents listed for the drug at issue (the active

pharmaceutical ingredient, or "API" patent). *Id*. at 1286. Ivax had not been sued, however, on the second Orange Book patent. *Id*.

Caraco, the second ANDA filer, was also in litigation with the patentee, Forest Laboratories ("Forest") on the API patent, and also was not sued on the second Orange Book patent. Caraco nonetheless brought an action for a declaratory judgment of noninfringement of the second patent, and subsequently received from Forest a covenant not to sue to "'to confirm' that there was no case or controversy between the parties." *Id*. at 1289.

Because it lost its validity challenge on the API patent, Ivax, the first-filer, cannot market its generic drug product until the API patent expires in 2012. *Caraco*, 527 F.3d at 1287. By virtue of losing its validity challenge on the API patent, Ivax also lost any entitlement to the 180-day exclusivity on that patent, but retained its entitlement to 180-day exclusivity on the second Orange Book patent, the patent at issue in Caraco's declaratory judgment action.[3]

The Federal Circuit in *Caraco*, in holding that jurisdiction existed on Caraco's declaratory judgment action on the second Orange Book patent despite the covenant not to sue, began by observing that any alleged injury, in order to support declaratory judgment jurisdiction after *MedImmune*, must be "concrete and actual or imminent, not conjectural or hypothetical." 527 F.3d at 1291 (internal quotation marks omitted) (quoting *Steel Co. v. Citizens for a Better*

[3] In *Caraco*, the Federal Circuit panel seems to have assumed incorrectly that the first-filer, Ivax, retained its 180-day exclusivity on the API patent that it lost its validity challenge on. 527 F.3d at 1287. However, after an unsuccessful patent challenge, the FDA regulations require a change in the ANDA's Paragraph IV certification to a Paragraph III certification (ANDA approval only after patent at issue expires) with the resulting loss of the 180-day exclusivity as to that patent. 21 C.F.R. § 314.94(a)(12)(viii)(A). (Exh. 5). Indeed, even though obviously trying to defend the Federal Circuit's decision against a request for rehearing filed by Forest and a number of *amici*, Caraco conceded in its response to the rehearing petitions that the Federal Circuit "overlooked the fact that Ivax lost its exclusivity on the '712 [API] patent when it lost its challenge to that patent." (Exh. 6, p. 15 n. 12).

*Env't*, 523 U.S. 83, 102-03 (1998)). Moreover, there must exist "but-for causation" linking the alleged injury to the conduct of the defendant. *Caraco*, 527 F.3d at 1292.

In holding that Caraco met these tests, the panel concluded that Forest's conduct in not suing Caraco (and in not subsequently stipulating to a judgment of noninfringement), was a but-for cause of delaying Caraco's ANDA approval. *Id*. Specifically, in the absence of the declaratory judgment action, Caraco could not trigger, ***and therefore eliminate***, the first-filer's 180-day exclusivity on the second Orange Book patent, which necessarily would delay Caraco's market entry by 180 days. *See Id.* at 1291-93.

The Federal Circuit therefore held that, under the precise facts of *Caraco,* there existed an actual and immediate alleged injury and but-for causation between the ability of Caraco to proceed with its declaratory judgment action and its market entry date. *Id*. at 1291-94. Indeed, the ability to eliminate Ivax's last-remaining basis for 180-day exclusivity on the declaratory judgment patent necessarily hastened Caraco's market entry, regardless of whether Caraco subsequently prevailed in the then-still pending API patent lawsuit. *Id*. As Caraco itself observed in its Response to the petition for rehearing in the Federal Circuit:

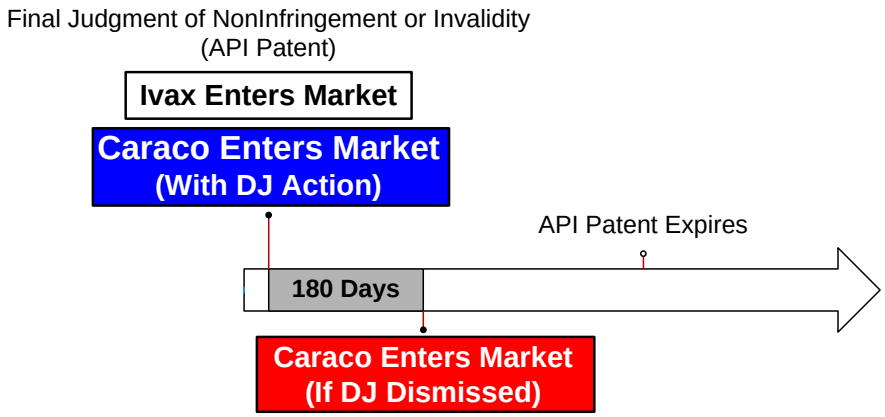
> A favorable ruling on the [declaratory judgment] patent is thus *guaranteed* to redress at least 180 days of market delay; and if Ivax were unable to enter the market when the [API] patent expired, it would redress much more. Thus, there is nothing speculative about Caraco's injury or a court's ability to redress it."

(Exh. 6, p. 15 (emphasis in original)).

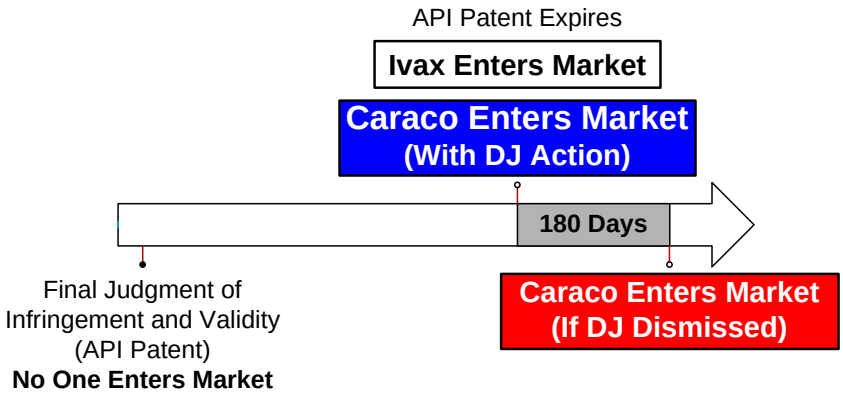
The following diagram demonstrates how Caraco's declaratory judgment action necessarily allowed Caraco earlier entry, regardless of whether it won its API patent challenge:

## Declaratory Judgment of NonInfringement Moves Up Caraco's Market Entry Regardless of the Outcome of Its API Patent Challenge

### Scenario I: Caraco Wins Its API Patent Challenge




### Scenario II: Caraco Loses Its API Patent Challenge




Thus, Caraco's ability to bring the declaratory judgment action actually and necessarily hastened its market entry, and the relief it sought through that action was not hypothetical or conjectural. *See Caraco*, 527 F.3d at 1291; *see also Steel Co.*, 523 U.S. at 102-03.

The long term precedential value of the *Caraco* decision is uncertain. The Supreme Court may take the case if and when petitions for *certiorari* are filed. Even at the Federal Circuit, there seems to be some skepticism about the rationale of the decision. In *Caraco*, the "injury" allegedly caused by the patentee was, essentially, the ability of the first-filer, Ivax, to retain its statutory 180-day exclusivity on the patent that was the subject of the declaratory judgment action. 527 F.3d at 1291-92. But the panel never directly addressed how to reconcile the first-filer's 180-day exclusivity as an "injury" with the well-recognized policy objective of the Hatch-Waxman Act, acknowledged by the panel, of rewarding the first-filer for expediting its ANDA filing through grant of this same 180 days. *See Id.* at 1283. In other words, the effect of *Caraco* is to strip the first-filer Ivax of its 180-day exclusivity even though it expedited the preparation of its ANDA as Congress intended.

Indeed, in a recent Federal Circuit argument involving an appeal of a dismissal of a declaratory judgment action brought by a non-first ANDA filer, a different panel appeared to question why the continued existence of the 180-day exclusivity is an "injury," as opposed to the Hatch-Waxman Act operating the way Congress intended.[4]

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[4] During the recent Federal Circuit argument in *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, No. 2008-1062 (Fed. Cir. argued July 7, 2008) involving dismissal of a declaratory judgment action in the face of a covenant not to sue, the panel asked: "Isn't the issue here that you [Apotex] are second in line and now you have to wait? I mean that's just what Hatch-Waxman says." (13:38); "You're talking about the policies of *MedImmune*, but we have to deal with the policies of the Hatch-Waxman Act too… we have to make sure the first filer, for instance, gets their 180 days of exclusivity. In this case, that's Teva [Ivax]. They're not here, but we have to worry about that because that's part of the Hatch-Waxman Act." (3:23); and "You just want to chew it all up while they can't actually market… that's not what the statute does. That might be what you think Hatch-Waxman was intended to do, but the statute doesn't do that." (4:06). *See* http://oralarguments.cafc.uscourts.gov/mp3/2008-1062.mp3, last visited August 10, 2008.

For now, *Caraco* is controlling precedent for those fact patterns that meet the "immediacy" of injury and "but-for" causation standards that it articulates. There is, however, no basis to extend *Caraco* beyond its precise facts to situations like the one present here, where the ability of Dey to affect the first-filer's 180-day exclusivity through this declaratory action is only "conjectural" or "hypothetical." *See Steel Co.*, 523 U.S. at 102-03.

Specifically, as discussed above, Breath, the first-filer, will enter the market pursuant to a license from Sepracor by August 20, 2012, a year before the expiration of the '994 patent on which Sepracor has sued Dey, and seven months before the expiration of the '755 patent. If Dey does not win on ***both*** of those patents, *i.e.*, if the Court finds that one of the six asserted claims from these two patents is valid, enforceable and infringed, then Dey will not be permitted to enter the market until more than 180 days after Breath begins marketing -- and thus after Breath's expected 180-day exclusivity has already expired. *See* 35 U.S.C. § 271(e)(4)(A). Thus, in contrast to the situation in *Caraco*, the ability of this declaratory judgment action to affect Dey's market entry date is completely speculative. *Cf. Caraco*, 527 F.3d at 1291 (the injury-in-fact alleged must be "concrete and actual or imminent, not conjectural or hypothetical.") (internal quotations omitted).

Indeed, if Dey does not prevail on all (or most) of the claim construction disputes presented to this Court at the recent Markman hearing in the pending lawsuit, the chance of Dey prevailing on each claim of the '994 and '755 patents goes from "hypothetical" to highly unlikely. Breath's expected 180 days will expire then before Dey is permitted to enter the market. Under such circumstances, where the possibility of relief from the injury alleged in the declaratory judgment action is completely speculative and not actual and immediate, there is no declaratory judgment jurisdiction. *See Pfizer, Inc. v Ranbaxy Labs. Ltd.*, 525 F. Supp. 2d at 686:

> Ranbaxy contends that because the covenant not to sue does not embrace any reissue of the '995 patent, subject matter jurisdiction still exists over its declaratory judgment counterclaims. However, the question of whether a new patent will ever be reissued is speculative, purely hypothetical and unripe for judicial determination. Accordingly, the Court concludes that these circumstances do not support jurisdiction under the *MedImmune* standard.

*See also Eisai Co., Ltd. v. Mutual Pharm. Co., Inc.*, No. 06-3613, 2007 WL 4556958, at *18 (D. N.J. Dec. 20, 2007) (no declaratory judgment jurisdiction in ANDA case where alleged injury "is not sufficiently immediate.").

In a companion case to *Caraco*, argued on the same day to the same panel, the Federal Circuit confirmed that there is no declaratory judgment jurisdiction in second-filer declaratory judgment cases if the first-filer's 180 days is triggered by events independent of the second filer's ability to obtain a judgment in its declaratory judgment action. *Merck & Co., Inc. v. Apotex, Inc.*, No. 2007-1362, 2008 WL 2753378, at *3 (Fed. Cir. July 16, 2008). Here, similarly, it is likely -- not just possible -- that Breath's expected 180-day exclusivity will be triggered by Breath's own marketing before that 180-day period would ever be a barrier to Dey's market entry.

Nor can Dey demonstrate that its hypothetical and arguably unlikely injury, delayed market entry, would not occur "but-for" Sepracor's conduct (in not suing Dey for infringement of the '289 patent). Although the *Caraco* panel acknowledged the "but-for" causation requirement (527 F.3d at 1292), it never really examined why the patentee's conduct, as opposed to Caraco's conduct, was the "but-for" cause of Caraco's delayed market entry.

Here, there is no reason Dey could not have filed its ANDA before it did, and more importantly, as quickly as Breath did. Dey cannot explain how Sepracor "caused" Breath's expected 180-day exclusivity for its earlier ANDA filing -- the very reward the framers of the

Hatch-Waxman Act envisioned -- as opposed to Dey's own "delay" having caused it. Nor can Dey explain why Breath's expected 180-day marketing advantage is not the result of Breath's efficiency and expedition in getting its ANDA on file quickly. Arguably, among these three companies, Sepracor had the least to do with the fact that Dey will have to wait for Breath to enjoy the 180-day exclusivity that the Hatch-Waxman Act framers intended that it have. Certainly, "but-for" causation linking Dey's hypothetical injury to Sepracor's alleged conduct is not established here. *See Steel Co.*, 523 U.S. at 102-03.

In this case, Dey's alleged injury is completely hypothetical at this point in time, and in any event has not been caused by Sepracor. Thus, there is no declaratory judgment jurisdiction and no basis for this Court to permit Dey's declaratory judgment action to go forward. *Id.*

**B. Under *MedImmune's* Totality Of The Circumstances Test, There Is No Case Or Controversy Here And No Declaratory Judgment Jurisdiction**

Because the facts of this case do not fit within the narrow exception that *Caraco* has carved out to the post-*MedImmune* line of cases that hold that a covenant not to sue divests the District Court of jurisdiction to hear a declaratory judgment counterclaim, the unqualified covenant given Dey on the '289 patent requires dismissal of this action. *See, e.g.*, *Pfizer*, 525 F. Supp. 2d at 686; *Janssen, Inc.*, 2007 WL 3014702, at *3 (D. N.J. 2007); *Merck & Co.*, 488 F. Supp. 2d at 425-26. Indeed, the totality of the circumstances in this case compels the conclusion that there is no case or controversy here:

- No one but Dey is to blame for not filing its ANDA before Breath did, in which case Dey would have had no barrier to market entry redressable by this declaratory judgment action, and would have been eligible for 180-day exclusivity over Breath and any other subsequent ANDA filers;

- Dey deliberately ignored the '289 patent for over two years during the existing litigation between the parties;

- Dey now has an unqualified covenant not to sue on the '289 patent;

- The ability of Dey to hasten its market entry through this declaratory judgment action is conjectural, if not unlikely, because any Breath exclusivity may very well expire before Dey is permitted to enter the market under the patents in the pending litigation;

- Whether or not this declaratory judgment action can in fact hasten Dey's market entry will not be known until after the Federal Circuit decides any appeal from the pending lawsuit;

- Breath's exclusivity does not prevent Dey from marketing its "concentrate" strength of generic Xopenex®, which is eligible for final FDA approval early in 2009; and

- Breath will trigger its own 180-day exclusivity in August of 2012.

Given that the totality of circumstances points to the lack of any current case or controversy, there is no subject matter jurisdiction. *See MedImmune*, 549 U.S. 118, 127 S. Ct. at 771.

**C. Even If The Court Is Not Required To Dismiss This Action For Lack Of Subject Matter Jurisdiction, It Should Exercise Its Discretion To Do So**

The *Caraco* decision only addressed whether a declaratory judgment action under the facts present in that case met the Constitutional requirements of a case or controversy. *Caraco* did not address and certainly did not attempt to change the law that holds that, even when the minimum Constitutional requirements for case or controversy are met, the Court's exercise of jurisdiction in a declaratory judgment action is still entirely discretionary.

Indeed, the Declaratory Judgment Act provides only that courts "***may*** declare the rights and other legal relations of any interested party" not that they must do so. 28 U.S.C. § 2201(a) (emphasis added). It is black letter law that "'there is … nothing automatic or obligatory about the assumption of "jurisdiction" by a federal court' to hear a declaratory judgment action." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 288 (1995) (quoting E. Borchard, DECLARATORY JUDGMENTS at 313 (2d ed. 1941)); *St. Clair Intellectual Prop. Consultants, Inc. v. Mirage Sys.*,

*Inc.*, 419 F. Supp. 2d 620, 623 (D. Del. 2006) ("a district court is authorized, in the sound exercise of its discretion, to stay or dismiss an action seeking a declaratory judgment.").

When deciding whether to hear a declaratory judgment action, this Court must consider pragmatism and judicial economy. "In the declaratory judgment context, the normal principle that federal courts should adjudicate claims within their jurisdiction ***yields to considerations of practicality and wise judicial administration***." *Wilton*, 515 U.S. at 288 (emphasis added). The Federal Circuit followed this view explaining that courts must consider whether hearing a case would "serve the objectives for which the Declaratory Judgment Act was created." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 814 (Fed. Cir. 1996), *overruled in part on other grounds, by MedImmune*.

Here, pragmatism and judicial economy counsel against accepting jurisdiction. Dey ignored the '289 patent for over two years, and now has an unqualified covenant not to sue. Even if this Court were to issue a ruling favorable to Dey in this lawsuit, Dey will still not be able to obtain FDA approval until there is a final decision that Sepracor's '755 and '994 patents are not infringed or are invalid -- an uncertain event at best. Thus any decision in this matter would be purely advisory and have no real-world consequences -- a circumstance long viewed as an objectionable waste of limited judicial resources. *See Coffman v. Breeze Corp.*, 323 U.S. 316, 324 (1945) (declaratory judgment proceedings "may not be made the medium for securing an advisory opinion in a controversy which has not arisen.").

Allowing Dey's suit would also open up the already overcrowded courts to many more cases where defendants drag patentees into court where there is no justiciable controversy. *See Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 889 (Fed. Cir. 1992) (A patent owner should not be forced to litigate and has the "right, either not to sue or not be provoked into suit…."); *EMC*

*Corp.*, 89 F.3d at 812 (declaratory judgment actions "should not be used to force unwanted litigation on quiescent patent owners.") (internal quotations omitted); *Hartford Fire Ins. Co. v. InterDigital Commc'ns Corp.*, 464 F. Supp. 2d 375, 382 (D. Del. 2006) (declining to exercise jurisdiction over a declaratory judgment count until completion of a related lawsuit).

In a post-*Caraco* dismissal of an ANDA-related declaratory judgment action, one District Court observed:

> Lastly, even if plaintiff's showing were sufficient to give rise to standing, the Court would, under the circumstances presented, use its substantial discretion in deciding whether to declare the rights of litigants, to decline to exercise jurisdiction over the instant action. In particular, plaintiff's allegation of jurisdiction rests on the existence of the '838 patent, plaintiff's filing an ANDA, and defendant's failure to immediately agree to a covenant not to sue. If, under such circumstances, the Court were to exercise declaratory judgment jurisdiction, it would promote the premature filing of declaratory judgment actions….

*Impax Labs. Inc. v. Medicis Pharm. Corp.*, No. 08-0253, 2008 WL 1767044, at *4 (N.D. Cal. April 16, 2008) (internal quotations and citation omitted).

In this case, the Court should exercise its discretion and dismiss Dey's premature declaratory judgment action. If, in the future, Dey prevails in Sepracor's pending action and at the Federal Circuit before Breath has begun marketing in 2012, and if *Caraco* remains good law at that point in time, Dey can then attempt to convince this Court to take on a lawsuit that the patentee has made clear through its unqualified covenant not to sue is completely unnecessary.

## CONCLUSION

For the foregoing reasons, Sepracor respectfully requests that the Court dismiss Dey's premature declaratory judgment action.

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August 13, 2008
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**CERTIFICATE OF SERVICE**

I, hereby certify that on August 13, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

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